Lilly Announces Positive Top-Line Phase 3 Results for Taltz® (ixekizumab) in Ankylosing Spondylitis (Radiographic Axial Spondyloarthritis)

February 13, 2018

INDIANAPOLIS, Feb. 13, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that Taltz® (ixekizumab) met the primary and all key secondary endpoints in COAST-V, a Phase 3 study evaluating the safety and efficacy of Taltz for the treatment of Ankylosing Spondylitis (AS), also known as radiographic axial spondyloarthritis (axSpA). The trial included a placebo arm and an active control arm (adalimumab) for comparison with placebo, and studied patients who had never received a biologic disease-modifying anti-rheumatic drug (bDMARD).

Taltz demonstrated a statistically significant improvement in the signs and symptoms of AS, as measured by the proportion of patients who achieved Assessment of Spondyloarthritis International Society 40 (ASAS40) response at 16 weeks, when compared to placebo. COAST-V is the first registration trial to use ASAS40 as the primary endpoint, compared to the standard endpoint of ASAS20.

AS is one type of spondyloarthritis that affects the pelvic joints and spine, and can be characterized by chronic inflammatory back pain, stiffness and impaired function and mobility.[1] Of those affected by AS, approximately 80 percent will experience symptoms before age 30.[2]

"Many people with this chronic, debilitating disease are still searching for an effective treatment. These initial results suggest that Taltz, if approved for this indication, may have the potential to help people with this challenging disease," said Dr. Lotus Mallbris, vice president and immunology platform team leader, Lilly Bio-Medicines. "At Lilly, the unmet needs of people living with autoimmune diseases drive our commitment to continue investing in novel science, developing medicines that may reduce the burden of disease and aim to raise the bar for treatment expectations."

In COAST-V, the incidence of treatment-emergent adverse events was similar with Taltz compared with placebo. The most common adverse events observed were consistent with the Phase 3 studies of ixekizumab for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis.

Lilly plans to submit detailed data from COAST-V for disclosure at scientific meetings and in peer-reviewed journals later this year. The company plans to submit for regulatory approvals pending additional data from the ongoing Taltz development program later this year.

Indications and Usage
Taltz is approved for the treatment of adults with active psoriatic arthritis. Taltz is also approved to treat adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections
Taltz may increase the risk of infection. In clinical trials of patients with plaque psoriasis, the Taltz group had a higher rate of infections than the placebo group (27% vs 23%). A similar increase in risk of infection was seen in placebo-controlled trials of patients with psoriatic arthritis. Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Taltz until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Taltz. Do not administer to patients with active TB infection. Initiate treatment of latent TB prior to administering Taltz. Closely monitor patients receiving Taltz for signs and symptoms of active TB during and after treatment.

Hypersensitivity
Serious hypersensitivity reactions, including angioedema and urticaria (each ≤0.1%), occurred in the Taltz group in clinical trials. Anaphylaxis, including cases leading to hospitalization, has been reported in post-marketing use with Taltz. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

Inflammatory Bowel Disease
During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease. Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials in patients with plaque psoriasis.

Immunizations

Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with Taltz.

ADVERSE REACTIONS
Most common adverse reactions (≥1%) associated with Taltz treatment are injection site reactions, upper respiratory tract infections, nausea, and tinea infections. Overall, the safety profile observed in patients with psoriatic arthritis was consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis.

Please click to access the Prescribing Information and Medication Guide. Please click to access Instructions for Use included with the device.

About the COAST-V Study
COAST-V is a multicenter, randomized, double-blind, active and placebo-controlled 16-week study followed by long-term evaluation of efficacy and safety of ixekizumab in biologic disease-modifying anti-rheumatic drug (bDMARD)-naïve patients with as Ankylosing Spondylitis (AS), also known as radiographic axial spondyloarthritis (axSpA). Patients were required to have an established diagnosis of AS with active disease defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Numeric Rating Scale (NRS) score ≥4 and a total back pain NRS score ≥4. During the study, ixekizumab-treated patients received a starting dose of 80-mg or 160-mg, followed by one of two dosing regimens: either 80-mg administered subcutaneously once every two weeks or 80-mg administered subcutaneously once every four weeks. Adalimumab at the approved dose of 40-mg, administered subcutaneously every two weeks, was selected as the active control for comparison with placebo. The COAST-V study will also evaluate the long-term efficacy and safety of ixekizumab in patients with AS up to one year.

About the Taltz Program in axSpA
The COAST-V study is part of a clinical development program that aims to evaluate the efficacy and safety of ixekizumab across various population subsets of patients with axSpA. The COAST program includes three registration studies each of one year duration: COAST-V in patients with AS/active radiographic axSpA who are bDMARD-naïve; COAST-W in patients with AS/active radiographic axSpA who previously had an inadequate response to TNF inhibitors; and COAST-X in patients with non-radiographic axSpA who are bDMARD-naïve. Patients may enroll into a long-term extension study after completion of any of the registration studies to receive ixekizumab treatment for up to an additional two years.

About Taltz®
Taltz® (ixekizumab) is a monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Taltz inhibits the release of pro-inflammatory cytokines and chemokines.

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and www.lilly.com/newsroom/social-channels. **P-LLY**

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Taltz (ixekizumab) as a potential treatment for Ankylosing Spondylitis, and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that Taltz will receive additional regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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[1] Spondyloarthritis. American College of Rheumatology website. http://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Spondyloarthritis. Accessed February 13, 2018.

[2] Sieper, J., Braun, J. Overview of axial spondyloarthritis. Clinician's Manual on Axial Spondyloarthritis. 2014; 11 (96): 84.

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